



# UNITED STATES PATENT AND TRADEMARK OFFICE

ck

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/666,205

09/18/2003

Wolfgang Stampfer

HL/95-22634/CIP

8858

324

7590

06/20/2006

CIBA SPECIALTY CHEMICALS CORPORATION

PATENT DEPARTMENT

540 WHITE PLAINS RD

P O BOX 2005

TARRYTOWN, NY 10591-9005

EXAMINER

PAK, YONG D

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |                                 |  |
|------------------------------|-------------------------------|---------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/666,205 | Applicant(s)<br>STAMPFER ET AL. |  |
|                              | Examiner<br>Yong D. Pak       | Art Unit<br>1652                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2006.  
 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.  
 4a) Of the above claim(s) 8,9 and 11-13 is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1-7,10,14,15 and 37-42 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.  
 10) ☒ The drawing(s) filed on 18 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☒ All b) ☐ Some \* c) ☐ None of:  
 1. ☒ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>see attached</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This application is a CIP of PCT/EP03/02439.

The amendment filed on April 11, 2006, amending claims 2 and 37 and canceling claims 16-36 and 43-44, has been entered.

Claims 1-15 and 37-42 are pending. Claims 8-9 and 11-13 are withdrawn.

Claims 1-7, 10, 14-15 and 37-42 are under consideration.

### ***Election/Restrictions***

Applicant's election without traverse of Group I (claims 1-15 and 37-42) in the reply filed on March 20, 2006 is acknowledged. Applicants failed to elect a species as outlined in the Restriction Requirement. During a telephone conversation with Mr. Mansfield on May 15, 2006, applicants elected the species, SEQ ID NO:3.

Claims 8-9 and 11-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 20, 2006.

### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

***Information Disclosure Statement***

The information disclosure statements (IDS) submitted on March 9, 2005, April 26, 2004 and February 29, 2004 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

***Drawings***

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, page 43 for example. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

***Claim Objections***

Claim 5 is objected to because of the following informalities: Claim 5 is objected for improper grammar. The claim recites the word "from" instead of "of" in line 2. Appropriate correction is required.

Claim 37 is objected to because of the following informalities: Claim 37 is objected for improper grammar. The claim recites the article "an" in the last line of the

Art Unit: 1652

claim. It appears that the article "an" is unnecessary. Lines 8-9 of claim 37 is missing a comma. Appropriate corrections are required.

Claims 37-42 are objected to because of the following informalities: Claims 37-42 are objected for improper grammar. The claims recites the article "An" instead of "The" in line 1 of the claims. Appropriate correction is required.

Claims 40 and 42 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 40 recites the limitation that the polypeptide has the sequence of SEQ ID NO:48. However, the parent claim, claim 37, also recites this limitation. Claim 42 recites the limitation that the polypeptide of claim 41 has all of the properties given in claim 41. However, the polypeptide of claim 41 has all of the properties recited in the claim.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 5-7, 10, 15, 37-42 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory subject matter.

Claims 1-3, 5-7, 10, 15, 37-42, as written, do not sufficiently distinguish over alcohol dehydrogenases as they exist naturally because the claims do not particularly

Art Unit: 1652

point out any non-naturally occurring differences between the claimed products and the naturally occurring products, such as being "isolated" or "purified". In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated" or "purified" as taught by the specification. See MPEP 2105.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 15 and 37 and claims 38-42 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 15 and 37 recite the phrases "shows stereospecific alcohol dehydrogenase activity", "showing alcohol dehydrogenase activity" and "displays an alcohol dehydrogenase activity". The metes and bounds of the phrases in the context of the claims are not clear. It is not clear to the Examiner how an enzyme "shows" or "displays" alcohol dehydrogenase activity. Examiner requests clarification of the above phrase. Examiner suggest amending the phrases as "having alcohol dehydrogenase activity".

Art Unit: 1652

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the phrase "bound to the molecule". The metes and bounds of this phrase are not clear to the Examiner. It is not clear to the Examiner if the "molecule" is the "biocatalyst". Therefore, it is not clear to the Examiner either from the specification or from the claim as to what the  $Zn^{2+}$  is bound to. Examiner requests clarification of the above phrase.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "the molecule" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the limitation "the enzyme" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the phrase "at least one polypeptide forming the whole or part of the enzyme". The metes and bounds of this phrase in the context of the above claim are not clear to the Examiner. It is not clear to the Examiner if the biocatalyst is made from more than one polypeptide. Therefore, it is not clear to the Examiner either from the specification or from the claims as to what applicants mean by the above phrase. Examiner requests clarification of the phrase.

Claim 37 and claims 38-42 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 recites the phrase "showing alcohol dehydrogenase activity of the sequence with SEQ ID NO:48". The metes and bounds of this phrase in the context of the claim are not clear to the Examiner. It is not clear to the Examiner if the "polypeptide" has the amino acid sequence of SEQ ID NO:48 and has alcohol dehydrogenase activity or if the "polypeptide" simply has the same enzymatic activity of SEQ ID NO:48 or variants thereof, i.e. alcohol dehydrogenase activity. Examiner requests clarification of the above phrase.



Art Unit: 1652

Claims 37-38 and claims 39-42 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 37-38 and recites the term "version". The metes and bounds of this term in the context of the claim are not clear to the Examiner. It is not clear to the Examiner if the term "version" encompasses mutants and variants. A perusal of the specification did not provide the Examiner with a specific definition for the above term. Therefore, it is not clear as to what applicants mean by the term "version". Examiner requests clarification of the above phrase.

Claims 37-39 and 42 and claims 40-41 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 37-39 and 42 recite the phrases "given under", "given as" and "given in", respectively. The metes and bounds of the phrases in the context of the claims are not clear. It is not clear to the Examiner if the recited amino acid sequence has the sequence of SEQ ID NO:48, or whether the sequences are representative members of a genus. Examiner suggests amending the phrase as, for example, "the amino acid sequence of SEQ ID NO:48" to clearly indicate that the sequence recited in the claim is the amino acid sequence of SEQ ID NO:48.

Art Unit: 1652

Claims 37 and claims 38-42 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 recite the phrase "insertions, sequence extension or deletions". The metes and bounds of the phrase in the context of the claim are not clear. It is not clear to the Examiner what is inserted, extended or deleted, i.e. amino acids or other compounds. Examiner suggests amending the phrase as, for example, "amino acid insertions..." to clearly indicate that the modifications involve amino acids.

Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 recites the phrase "conditions just given for the temperature optimum". The metes and bounds of the phrase in the context of the claims are not clear. It is not clear to the Examiner as to what conditions are encompassed in the phrase. Therefore, it is unclear from the claim as to what applicants mean by the above phrase. Examiner requests clarification of the above phrase.

Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 is missing a conjunction between lines 11 and 12. Examiner requests clarification of the above phrase.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 10, 14-15, 37 and 41-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-7, 10, 14-15, 37 and 41-42 are drawn to (A) polypeptides obtained from *Rhodococcus* or *R. rubber* DSM 14855 having alcohol dehydrogenase activity and the recited properties, (B) polypeptides obtained from *Rhodococcus* comprising the partial sequence consisting of SEQ ID NO:3 and (C) variants of the polypeptide having the amino acid sequence of SEQ ID NO:48, comprising insertions, sequence extensions or deletions or combinations of two or more thereof, and having alcohol dehydrogenase activity and the recited properties. The claims encompass (A) any or all alcohol dehydrogenase obtained from any *Rhodococcus* or *R. rubber* DSM 14855, including any or all mutants, recombinants or variants thereof, (B) any or all alcohol

Art Unit: 1652

dehydrogenase obtained from any *Rhodococcus*, including any or all mutants, recombinants or variants thereof, comprising SEQ ID NO:3 and any other amino acid modifications and (C) any or all variants, mutants and recombinants of SEQ ID NO:48. More specifically, the limitation of (B) comprising SEQ ID NO:3 provides no description on the structure of other parts of the alcohol dehydrogenase. Therefore, the claims are drawn to a genus of polypeptides having alcohol dehydrogenase activity and having any structure, including any or all recombinants, mutants and variants. The specification only describes one representative species, a polypeptide having the amino acid sequence of SEQ ID NO:48, which comprises SEQ ID NO:3, and having alcohol dehydrogenase activity. One species is not enough and does not constitute a representative number of species to describe the whole genus and there is no evidence on the record of the relationship between the structure of an alcohol dehydrogenase of SEQ ID NO:48 and the structure of any alcohol dehydrogenase, including any or all recombinants, variants and mutants. Therefore, the specification fails to describe a representative species of the genus comprising any or all alcohol dehydrogenase obtained from *Rhodococcus*, including any or all variants, recombinants and mutants and any or all variants, mutants and recombinants of SEQ ID NO:48.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 1-7, 10, 14-15, 37 and 41-42.

Art Unit: 1652

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

Claims 1-7, 10, 14-15, 37-39 and 41-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide having the amino acid sequence of SEQ ID NO:48, which comprises SEQ ID NO:3, and having alcohol dehydrogenase activity, does not reasonably provide enablement for (A) polypeptides obtained from *Rhodococcus* or *R. rubber* DSM 14855 having alcohol dehydrogenase activity and the recited properties, (B) polypeptides obtained from *Rhodococcus* comprising the partial sequence consisting of SEQ ID NO:3 and (C) variants of the polypeptide having the amino acid sequence of SEQ ID NO:48, comprising insertions, sequence extensions or deletions or combinations of two or more thereof, and having alcohol dehydrogenase activity and the recited properties. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in

Art Unit: 1652

the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claims 1-7, 10, 14-15, 37 and 41-42 are drawn to (A) polypeptides obtained from *Rhodococcus* or *R. rubber* DSM 14855 having alcohol dehydrogenase activity and the recited properties, (B) polypeptides obtained from *Rhodococcus* comprising the partial sequence consisting of SEQ ID NO:3 and (C) variants of the polypeptide having the amino acid sequence of SEQ ID NO:48, comprising insertions, sequence extensions or deletions or combinations of two or more thereof, and having alcohol dehydrogenase activity and the recited properties. The claims encompass (A) any or all alcohol dehydrogenase obtained from any *Rhodococcus* or *R. rubber* DSM 14855, including any or all mutants, recombinants or variants thereof, (B) any or all alcohol dehydrogenase obtained from any *Rhodococcus*, including any or all mutants, recombinants or variants thereof, comprising SEQ ID NO:3 and any other amino acid modifications and (C) any or all variants, mutants and recombinants of SEQ ID NO:48. The limitation of (B) comprising SEQ ID NO:3 provides no description on the structure of other parts of the alcohol dehydrogenase. Therefore, the claims are drawn to alcohol dehydrogenases having any structure, including any or all recombinants, mutants and variants. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of any or all alcohol dehydrogenase obtained from *Rhodococcus*, including any or all variants, recombinants and mutants and any or all variants, mutants and recombinants of SEQ ID NO:48, broadly encompassed by the claims.

Since the amino acid sequence of the encoded protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to a polypeptide having the amino acid sequence of SEQ ID NO:48, which comprises SEQ ID NO:3, and having alcohol dehydrogenase activity. It would require undue experimentation of the skilled artisan to produce any or all alcohol dehydrogenases obtained from *Rhodococcus*, including any or all variants, mutants and recombinants thereof, or any or all mutants, variants and recombinants of SEQ ID NO:48. In view of the great breadth of the claim, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure, the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by the claims.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in

Art Unit: 1652

any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass any or all alcohol dehydrogenase obtained from *Rhodococcus*, including any or all variants, recombinants and mutants and any or all variants, mutants and recombinants of SEQ ID NO:48, because the specification does not establish: (A) regions of the structure of an alcohol dehydrogenase which may be modified without effecting its activity; (B) the general tolerance of an alcohol dehydrogenase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any or all alcohol dehydrogenase obtained from *Rhodococcus*, including any or all variants, recombinants and mutants and any or all variants, mutants and recombinants of SEQ ID NO:48. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of an alcohol dehydrogenase having the desired biological characteristics recited in the claim is unpredictable and the experimentation left to those skilled in the art is unnecessarily,



Art Unit: 1652

and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a novel microorganism. Since the microorganism is essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. All the sequences required for their construction have not been shown to be publicly known and freely available. The enablement requirements of 35 U.S.C. 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the DNA sequences are readily available to the public. Accordingly, it is deemed that a deposit of the microorganism be made in accordance with 37 CFR 1.801-1.809.

It is noted that if applicants have deposited the plasmid, it must be publicly available. If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be available to the public under the conditions specified in 37 CFR 1.808, would satisfy the deposit requirement made herein.

Art Unit: 1652

If the deposit has not been made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that: 1. during the pendency of this application, access to the invention will be afforded to the Commissioner upon request; 2. upon granting of the patent the strain will be available to the public under the conditions specified in 37 CFR 1.808; 3. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and 4. the deposit will be replaced if it should ever become inviable.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-7, 14-15, 37 and 41-42 are rejected under 35 U.S.C. 102(b) as being by Wang et al.

Claims 1, 3-7, 14-15, 37 and 41-42 are drawn to an alcohol dehydrogenase obtained from *Rhodococcus* having the recited properties and a version of SEQ ID

NO:48 having insertions, sequence extensions or deletions or combinations of two or more thereof.

Wang et al. (Appl Microbiol Biotechnol. 1999 Sep;52(3):386-92 – form PTO-892) discloses a recombinant alcohol dehydrogenase obtained from *Rhodococcus* (pages 387 and Figure 1 on page 389). The alcohol dehydrogenase of Wang et al. has stereospecific alcohol dehydrogenase activity in the reduction of secondary ketones (page 386), has a molecular weight of 32-44 kDa as determined from a SDS gel (page 389), and has a  $Zn^{+2}$  bound to its structure (pages 388 and 389). Since applicants have not placed any limitations in the amino acid changes of SEQ ID NO:48, the alcohol dehydrogenase of Wang et al. reads on an a polypeptide having the amino acid sequence of SEQ ID NO:48 comprising two or more insertions, sequence extensions or deletions or combinations. The alcohol dehydrogenase of Wang et al. inherently possesses the same material structure and functional characteristics as the alcohol dehydrogenase claimed herein since both alcohol dehydrogenases are obtained from *Rhodococcus* and reduces secondary ketones. Since the Office does not have facilities for examining and comparing applicant's alcohol dehydrogenase with the alcohol dehydrogenase of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the alcohol dehydrogenase of the prior art does not possess the same material structure and functional characteristics of the claimed alcohol dehydrogenase). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205

Art Unit: 1652

USPQ 594. Therefore, the reference of Wang et al. anticipates claims 1, 3-7, 14-15, 37 and 41-42.

Claims 1-7, 10, 14-15 and 37-42 are rejected under 35 U.S.C. 102(a) as being by Wang et al.

Claims 1-7, 10, 14-15 and 37-42 are drawn to an alcohol dehydrogenase obtained from *Rhodococcus ruber* DSM 14855 having the recited properties.

Stampfer et al. (form PTO-1449) discloses a recombinant alcohol dehydrogenase obtained from *Rhodococcus ruber* DSM 44541 (page 1014-1015). The specification on page 49 teaches that *Rhodococcus ruber* DSM 14855 and *Rhodococcus ruber* DSM 44541 are the same microorganism and methods of isolation of the enzyme are identical (pages 42-49 of the instant specification and page 1016). Therefore, the alcohol dehydrogenase of Stampfer et al. is 100% identical to the alcohol dehydrogenase of SEQ ID NO:48 of the instant invention, and comprises SEQ ID NO:3. The alcohol dehydrogenase of Stampfer has stereospecific alcohol dehydrogenase activity in the reduction of secondary ketones (page 1014) and has dehydrogenase activity in the presence of up to 50% by volume of isopropanol or 20% by volume of acetone (page 1014). The alcohol dehydrogenase of Wang et al. inherently possesses the same material structure and functional characteristics as the alcohol dehydrogenase of claims 5-7, 15 and 41-42 since both alcohol dehydrogenases are obtained from the same source and have identical structure. Since the Office does not have facilities for examining and comparing applicant's alcohol dehydrogenase with the alcohol

Art Unit: 1652

dehydrogenase of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the alcohol dehydrogenase of the prior art does not possess the same material structure and functional characteristics of the claimed alcohol dehydrogenase). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594. Examiner notes that the reference of Stampfer et al. was published online on March 15, 2002, before the filing date of applicant's priority document, EP 02 405 204.5, which was filed on March 18, 2002 (See Stampfer et al. – Online Publication Date – form PTO-892). Therefore, the reference of Stampfer et al. anticipates claims 1-7, 10, 14-15 and 37-42.

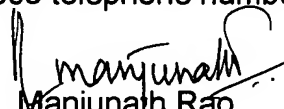
None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak  
Patent Examiner 1652

  
Manjunath Rao  
Primary Patent Examiner 1652